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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Supplemental Record of Decision; Final Supplementary Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratories

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SUMMARY: The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Supplementary Risk Assessment and a thorough consideration of public comments on the Draft and Final Supplementary Risk Assessment, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final Environmental Impact Statement (EIS). This action reaffirms the NIH's previous decision to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Campus (BUMC) in Boston, Massachusetts.

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SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH), an
operating division of the Department of Health and Human Services (HHS), has decided,
after completion of a Final Supplementary Risk Assessment for the Boston University
(BU) National Emerging Infectious Diseases Laboratories (NEIDL) and a thorough
consideration of the public comments on the Draft and Final Supplementary Risk
Assessments, that the NEIDL, in its current location in the BioSquare Research Park,
poses minimal risk to the community surrounding the facility. The Final Supplementary
Risk Assessment extensively evaluated scenarios involving the potential human health
consequences of an exposure to laboratory workers and members of the general public as
a result of unintentional or malevolent events. The Final Supplementary Risk
Assessment also analyzed the potential human health impacts of siting the NEIDL at two
alternate locations from the current site in Boston. The Final Supplementary Risk
Assessment concluded that the risk to the public was generally low, regardless of where
the facility was located. The analysis also showed there was no disproportionate impact

to the residents living in the environmental justice communities adjacent to the NEIDL's current location or to any environmental justice communities at either of the two alternative locations analyzed. Based on the results of the Final Supplementary Risk Assessment, NIH is reaffirming its prior Record of Decision of January 26, 2006, published in the Federal Register on February 2, 2006.

On January 26, 2006, the NIH signed the Record of Decision (ROD) to partially fund the construction of a state-of-the-art National Biocontainment Laboratory, which is now known as the NEIDL, on the Boston University Medical Campus in Boston, Massachusetts. The NEIDL is a research facility that was designed to include high- and maximum-containment laboratories for research on emerging and re-emerging infectious diseases. The ROD was posted in the Federal Register on February 2, 2006, and described the Proposed Action and alternatives considered in the NIH's Environmental Impact Statement for the NEIDL. The ROD also described many of the physical characteristics of the NEIDL and the safeguards that would be in place for research conducted in the building.

After the ROD was released, some members of the public continued to have concerns about the safety and environmental impact of the facility. Several citizens and public interest groups filed lawsuits in Federal court to stop the NIH's partial funding of the NEIDL's construction. Opponents also filed a lawsuit in Massachusetts state court challenging the state's approval of the project. Both lawsuits alleged failure to adequately assess the potential impacts of the NEIDL on public health in alternative locations. In the Federal court proceedings, questions were raised specifically about the potential risks of the biosafety level 4 (BSL-4) laboratory. To address the concerns

raised in these lawsuits, NIH established an independent Blue Ribbon Panel to advise the agency on comprehensively responding to the concerns raised by members of the community and by the courts. The Blue Ribbon Panel was established as a working group of the Advisory Committee to the NIH Director and was comprised of experts in infectious diseases, public health and epidemiology, risk assessment, environmental justice, risk communications, biosafety, and infectious disease modeling. At multiple points during the preparation of the Supplementary Risk Assessment, the NIH also consulted the National Research Council (NRC) Committee on Technical Input that had been critical of a previous draft NIH risk assessment for the NEIDL. With the technical and scientific guidance of the Blue Ribbon Panel and the NRC Committee on Technical Input as well as extensive public input, NIH prepared a Draft Supplementary Risk Assessment, which was published in the Federal Register on February 24, 2012. The publication of the Draft Supplementary Risk Assessment in the Federal Register began a 67-day public comment period. After a thorough consideration of comments received on the Draft Supplementary Risk Assessment, including those comments received during a public meeting held in Boston on April 19, 2012, NIH prepared a Final Supplementary Risk Assessment, notice of which was published in the Federal Register on July 6, 2012.

DECISION

After careful consideration of the information and analyses presented in the Final Supplementary Risk Assessment, including the potential impacts on public health and safety arising from research involving infectious agents, as well as all public comments received during and after the assessment's preparation, the NIH has decided to

reaffirm the decision reached in the agency's initial Record of Decision to implement the Selected Alternative, to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Campus (BUMC) in Boston, Massachusetts described in the December 2005 Final EIS. The additional information provided from the Final Supplementary Risk Assessment results has reinforced the agency's original decision. The NIH's decision to reaffirm the ROD does not commit the NIH to support any specific research in the NEIDL in the future.

ALTERNATIVES CONSIDERED

The Final Supplementary Risk Assessment considered and compared the potential public health impacts of a biocontainment failure at three separate, proposed locations for the NEIDL. Those locations included an urban (the current BUMC site), a suburban (Tyngsborough, MA), and a rural (Peterborough, NH) setting. The results of the Supplementary Risk Assessment showed minimal differences in the risks of infections or fatalities to lab workers at the three different sites because the laboratory and its operations would be the same at all three sites. There are differences in the three sites with regard to population density and other features of the environment, such as availability of medical care. The possible effects of these differences on risks to the public were evaluated. The results show that no statistically significant differences can be concluded at the suburban and rural sites (Peterborough and Tyngsborough) compared to the urban site (Boston).

FACTORS INVOLVED IN THE DECISION

Throughout the course of the project, NIH engaged in extensive consultations with the Boston community. During the development of the Supplementary Risk Assessment for the NEIDL, public input was sought and considered multiple times before the report was finalized. In preparing its advice to the NIH for the Supplementary Risk Assessment, the Blue Ribbon Panel held multiple public meetings, including several in Boston at locations suggested by community members, to hear the concerns of the community and to solicit input on what scenarios and agents the community wished to see analyzed in the document. The approach taken to perform the Supplementary Risk Assessment, as well as the types of scenarios and agents studied in the Supplementary Risk Assessment, were thoroughly discussed and publicly vetted through the Blue Ribbon Panel and the NRC Committee on Technical Input. These two independent bodies provided technical advice that was then used to guide NIH through the risk assessment process. In order to help ensure that the Supplementary Risk Assessment was as comprehensive and technically and scientifically sound as possible, the NIH contracted with a leading consulting firm to perform the assessment. This firm engaged outside experts in infectious diseases and modeling to assist in preparing the assessment.

After extensive consultations with the Blue Ribbon Panel, the NRC Committee on Technical Input, and the public, the contractor preparing the Supplementary Risk Assessment identified and considered approximately 300 events that could potentially lead to loss of containment. The contractor grouped these 300 events initially into 30 categories of related events. Based on their likely risk, several of these events were selected to represent the overall group. The selected events include higher- and lower-

risk events that occur in a variety of ways and expose different groups of people or the environment. Taking these factors into account, the possible events selected for detailed analysis in the Final Supplementary Risk Assessment were a needlestick accident, a centrifuge aerosol release, an earthquake, and transportation accidents.

To ensure examination of consequences with the most negative possible outcomes, mitigating features of the building systems, fully functional personal protective equipment, and standard operating procedures were not taken into account in the Supplementary Risk Assessment, which increased the risk by posing failures without taking into account mitigating features. For example, for purposes of the risk assessment, it was assumed that a needlestick would not be recognized and reported. Similarly, the risk assessment considered what would happen if a centrifuge release went undetected and unreported. In reality, lab personnel are trained to recognize and report such incidents, thus mitigating the consequences should such a lab accident occur.

The Final Supplementary Risk Assessment examined a variety of possible situations—including those that posed the maximum realistically expected risk that might expose laboratory workers and the general public to disease-causing microbes that will be studied in the NEIDL. While there is no such thing as “no risk”, the results of the analysis showed that the risk of infections or fatalities resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. The risk assessment evaluated the NEIDL and proposed activities in its laboratories as well as the potential impacts to site-specific populations in the three alternative geographic locations.

PRACTICABLE MEANS TO AVOID OR MINIMIZE POTENTIAL

ENVIRONMENTAL HARM FROM THE SELECTED ALTERNATIVE

All practicable means to avoid or minimize adverse environmental effects from the selected action have been identified and adopted. The NEIDL will be subject to oversight by numerous federal, state, and local entities including, but not limited to, the Centers for Disease Control (CDC) and Prevention, the NIH, and the Boston Public Health Commission. The NEIDL will also be subject to federal, state, and local pollution prevention, waste management, and environmental regulations. This level of oversight and regulation, in addition to NEIDL-specific laboratory standard operating procedures and researcher training should greatly minimize any chance of a pathogen being released into the environment.

MONITORING AND ENFORCEMENT PROGRAM FOR MITIGATION MEASURES

Boston University has established policies and procedures to ensure that the NEIDL complies with all applicable Federal, state, and local regulations. In addition, trained biosafety staff at Boston University will perform periodic laboratory inspections to ensure safety standards are rigorously upheld. Laboratory inspections will also be performed by the Boston Public Health Commission. The CDC will also perform inspections for those laboratories performing research with Select Agents. Projects requiring the use of BSL-3 and BSL-4 containment must be reviewed and approved by the Boston University Institutional Biosafety Committee (IBC). The Boston University IBC includes at least two members from the public who are not affiliated with Boston University. The Boston Public Health Commission will also review and approve projects

requiring BL3 or BL4 containment. Finally, as an NIH grantee, Boston University is required to comply with the grant terms and conditions. These terms and conditions require Boston University to file an annual progress report with NIH that describes the use of any highly pathogenic agents or Select Agents in the past year.

CONCLUSION

The Final Supplementary Risk Assessment examined a variety of possible scenarios, including those that posed the maximum realistic risk that might result in laboratory workers or the general public having primary or secondary infections resulting from release of pathogens that might be studied in the NEIDL. While there can be no such thing as “no risk,” the results of this analysis show that the risk of infections resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. This is largely due to the safeguards built into the facility, the low amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into everyday practice at the NEIDL and as well as due to oversight of the NEIDL by regulatory authorities, like the Boston Public Health Commission and the Centers for Disease Control and Prevention. The greatest risk posed by research in the NEIDL is to individuals conducting research in the building, not to the general public. The analysis did not show any statistically significant increase in risk to medically vulnerable populations when analyzed as a group or individually, as compared to what those risks would be at alternate sites. Based on these factors, NIH is reaffirming its prior Record of Decision, dated January 26, 2006, and concludes that high and maximum

containment research could be conducted safely at the NEIDL based upon the current safeguards and engineering controls in place at the facility.

Dated: December 18, 2012

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